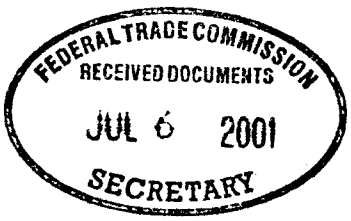
PUBLIC VERSION



In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation	)	

REPLY IN SUPPORT OF SCHERING-PLOUGH'S MOTION FOR PARTIAL DISMISSAL OF THE COMPLAINT

A. The Complaint Fails To Allege That Schering's Patent Was Either Invalid or Not Infringed.

In its Memorandum in support of its motion for partial dismissal of the Complaint ("Memorandum"), Schering-Plough Corporation ("Schering") pointed out that the Complaint fails to allege either that Schering's K-Dur patent is invalid or that it was not infringed by the Upsher and ESI products. Schering pointed out that this was a critical failure because unless its patent was invalid or not infringed, Schering had an absolute legal right to exclude Upsher and ESI's products from the market for *the entire* life of its patent. Obviously, Schering could also exclude those products from the market for *part* of the life of its patent – and that is what the challenged settlement agreements do.

In its Response, complaint counsel asserts that the questions whether Schering's patent is valid, and whether the Upsher and ESI products infringed it, are "*irrelevant.*"[1] It is apparently complaint counsel's position that even if Schering's patent is valid, and even if Upsher and ESI's products infringed it, Schering still may not enter into agreements excluding those products from the market during the life of the patent.

In an effort to support this odd position, complaint counsel cites several Supreme Court cases in which agreements between a patent holder and a competitor have been held to violate the antitrust laws, regardless of whether the competitor's product infringed a valid patent.[2] These cases do not help complaint counsel at all. In these cases the patent holder extracted by agreement something that was outside the scope of, and beyond the limits of, its legal patent monopoly. Indeed, in three of these cases, the patent holder and the competitor agreed to fix prices on the patented products.[3]

United States v. Masonite, 316 U.S. 265 (1942), is the first case cited by complaint counsel. There, Masonite had sued Celotex for infringement of its patent. The court of appeals held Masonite's patent was valid and infringed. While a petition for certiorari was pending, Masonite and Celotex settled and entered into an agreement pursuant to which Masonite licensed Celotex under the patent, and Celotex agreed to sell the Masonite product covered by the patent at prices dictated by Masonite. *Id.* at 271. Shortly thereafter, Masonite entered into similar price fixing agreements with other companies which it licensed to sell its patented product. *Id.* at 269.

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1 *See* complaint counsel's Response to Schering's Motion for Partial Dismissal of the Complaint (hereinafter "Response") at 9.

2 *United States v. Masonite*, 316 U.S. 265 (1942); *United States v. Line Material Co.*, 333 U.S. 287 (1948); *United States v. New Wrinkle*, 342 U.S. 371 (1952); *United States v. Singer*, 374 U.S. 174 (1963).

3 *See Masonite, Line Materials* and *New Wrinkle, supra.*

The Supreme Court held that the agreements were price-fixing agreements in violation of the Sherman Act, 15 U.S.C. § 1. *Id.* at 274. The Court rejected Masonite's contention that its patent gave it the right to dictate the prices at which its product was sold:

> The owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly within the grant. We have recently stated in *Morton Salt Co. v. Suppinger Co.*, 314 U.S. 488, 492, that "the public policy which includes inventions within the granted monopoly excludes from it that which is not embraced within the invention. It equally forbids the use of the patent to secure an exclusive right or limited monopoly not granted by the Patent Office and which it is contrary to public policy to grant."

Id. at 277. Thus, because Masonite's patent did not give it the right to fix prices with a licensee, the agreements were held to violate the Sherman Act.

United States v. Line Material Co., 333 U.S. 287 (1948), and *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952), also involved price-setting licenses. In *Line Material*, the Court held that where patents are cross-licensed, a provision in a sublicense dictating the prices to be charged by the sublicensee violates the Sherman Act. 333 U.S. at 288-299, 305-315. The Court reasoned that this arrangement transcended the legitimate use of the patent monopoly: "the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act *beyond the limits of the patent monopoly*. *Id.* at 308 (emphasis added). In *New Wrinkle*, the Court struck down a patent-pooling arrangement that included a price-setting provision on the same ground. 342 U.S. 371, 380.[4]

The settlement agreements at issue here do not give Schering anything beyond the limits of its legal patent monopoly. Schering has not sought to control the prices to be charged by Upsher or ESI when they enter the market. The agreements only give the Schering that which is

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[4] In *United States v. Singer*, 374 U.S. 174 (1963), the Court concluded that Singer had conspired with Swiss and Italian competitors to engage in a number of practices, including patent-pooling arrangements, designed to exclude Japanese competitors from the market. *Id.* at 193-96. Moreover, the record suggested that part of the parties' reason for settling interference proceedings was to avoid drawing attention to prior art that called into question the validity of their patents. *Id.* at 199 (White, J., concurring). The Court concluded that Singer's actions "went far beyond its claimed purpose of merely protecting its own [product];" it was also protecting its competitors and co-conspirators. *Id.* at 194.

squarely within the scope of its lawful patent monopoly: the right to exclude infringing competitors during the life of the patent.

Where a patent holder enters an agreement with a licensee that gives the patent holder only that which is within the scope of its legal patent monopoly, then the agreement is not illegal. "[T]he patentee may grant a license 'upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure.'" *General Talking Pictures Co. v. Western Elec. Co.*, 305 U.S. 124, 127 (1938) (citation omitted). Thus, a patent holder "may grant licenses to make, use or vend, restricted in point of space or time, or with any other restriction upon the exercise of the granted privilege, save only that by attaching a condition to his license he may not enlarge his monopoly and thus acquire some other which the statute and the patent together did not give." *Ethyl Gasoline Corp. v. United States,* 309 U.S. 436, 456 (1940).

United States v. CIBA Geigy Corp., 508 F. Supp. 1118 (D.N.J. 1976), is an illustration of this principle. There, CIBA held a patent for a certain drug and entered into license agreements with other drug companies, such as Abbott, to sell that drug. These agreements contained certain post-sale restrictions, including restrictions on bulk sales and on the licensee's use of the drug. The government alleged that these agreements violated section 1 of the Sherman Act. The court concluded that a limitation to certain types of sales did not transcend the bounds of CIBA's patent. Instead, the court concluded that "[t]he inescapable fact is that the license to Abbott opened up competition in an area in which CIBA had the legal right to shut off all competition. To say that CIBA 'restrained competition' by not licensing Abbott in as unlimited a fashion as was possible is to impose a duty upon the patentee that simply is not justifiable." *Id.* at 1151.

This case is governed by the proposition set forth in the Hovenkamp treatise cited in Schering's Memorandum. A plaintiff in a patent lawsuit may settle that lawsuit on terms that give it relief that is within the scope of a "likely outcome of the litigation." 12 Herbert Hovenkamp, *Antitrust Law,* ¶ 2046 at 265-66 (1999). This assures that the settlement agreement

will not provide the patent holder with relief that is "beyond the limits of its [lawful] patent monopoly."

Here, Schering obtained agreements from Upsher and ESI that they would not market their allegedly infringing products for part of the remaining life of the patent. This was relief that was within the scope of its lawful patent monopoly, and it was within the scope of a likely outcome of the litigation. Without an allegation that Schering's patent was invalid, or that the Upsher or ESI generics did not infringe the patent, no illegality is alleged at all. And the Complaint should be dismissed.

B. The Complaint Does Not Allege that the Settlements Are Worse For Consumers Than Continued Litigation Would Have Been

Schering pointed out in its initial Memorandum that the settlement agreements permitted the Upsher and ESI's products to enter the market before the expiration of Schering's patent: five years before patent expiration in the case of Upsher, and two and a half years before patent expiration in the case of ESI. Thus, under the settlements, Upsher was able to market its product for a significant part of the remaining life of the patent, and ESI was able to market its product for a smaller but not insignificant part of the remaining life of the patent.

Schering then pointed out that the Complaint fails to allege that these settlement agreements were less favorable for competition or consumers than continued litigation would have been. In other words, the Complaint fails to allege that the split of the remaining patent life was anything other than an objective reflection of the strength of the parties' respective litigation positions. This is also a critical failure. Obviously if the split of the remaining patent life agreed to in the settlements accurately reflected the strength of the respective parties' litigating positions, the settlements are as good for competition as continued litigation.

In its response, complaint counsel makes an astonishing assertion. Complaint counsel writes "Schering's, Upsher-Smith's or AHP's Chances of Winning the Patent Suit are Irrelevant

to Determining Whether The Settlement Harmed Competition."[5] Thus, according to complaint counsel, if Schering had a 99% chance of winning both patent suits, the settlements would still harm competition. This, of course, is nonsense.

Elsewhere in its response, complaint counsel shows that it knows full well how important the likely outcome of the patent litigation is to this case. Complaint counsel asserts, at page 8 of its Response, that under the settlements Schering "obtained a longer monopoly life *than it expected to get if it litigated the cases* or settled without the payments."

This statement shows that complaint counsel is acutely aware of the importance of the "expected" or probable outcome of the litigation; and that complaint counsel knows that the settlements are anticompetitive only if the split of the patent life under the settlements was worse for competition than the probable outcome of the litigation. But the Complaint fails to allege anything on this subject. And without an allegation that the settlements are worse for consumers than continued litigation would have been, the Complaint simply alleges that the patent cases were settled with no adverse effect on competition. And the Complaint should be dismissed for failure to state a claim.[6]

C. If Complaint Counsel Must *Prove* Invalidity or Non-Infringement the Complaint Must *Allege* Invalidity or Non-Infringement

Complaint counsel also argues that the Complaint alleges that the settlement agreements violate the antitrust laws, at least in conclusory terms; and that the Complaint gives Schering adequate "notice" of the claims made against it. Complaint counsel argues that this is enough. Apparently, complaint counsel believes that, even if it is wrong on the key legal issues discussed

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5 *See* Response at 13.

6 Complaint counsel also rely on district court decisions in the Hoechst/Andrx and Abbott/Geneva matters for the proposition that the merits of the underlying patent litigation are irrelevant. Response at 17. The district court decisions in these cases are not on point. In each case, the courts were at pains to point out that the agreements involved there were *not* settlement agreements; thus, the law applicable to such agreements was not implicated. *In re Cardizem CD Antitrust Litigation*, 105 F.Supp.2d 682, 704-05 (E.D. Mich. 2000); *In re Terazosin Hydrochloride Antitrust Litigation*, 2000 U.S. Dist. LEXIS 20477, at *29-30 (S.D. Fla. Dec. 13, 2000).

above, and even if validity, infringement, and the likely outcome of the patent litigation are critical to the case, it still need not make any allegations concerning those issues in the Complaint. The case law, however, points in another direction.

It is hornbook law that a complaint must contain "either direct allegations on every material point necessary to sustain a recovery on any legal theory or contain allegations from which an inference fairly may be drawn that evidence on these material points will be introduced at trial." 5 C. Wright & A. Miller, Federal Practice & Procedure § 1216 at 121-23 (1969). "[T]he pleader will not be allowed to evade this requirement by attaching a bare legal conclusion to the facts that he narrates: if he claims an antitrust violation, but the facts he narrates do not at least adumbrate such a violation, he will get nowhere merely by dressing them up in the language of antitrust." *Sutliff, Inc. v. Donovan Cos., Inc.*, 727 F.2d 648, 654 (7th Cir. 1984).

Thus, it is true that a "plaintiff will not be thrown out of court for failing to plead facts in support of every arcane element of his claim. But when a complaint omits facts that, if they existed, would clearly dominate the case, it seems fair to assume that those facts do not exist." *O'Brien v. DiGrazia*, 544 F.2d 543, 546 n.3 (1st Cir. 1976), *cert. denied,* 431 U.S. 914 (1977).

Here the questions of validity, infringement and the likelihood of success in the underlying litigation dominate this case. If complaint counsel is not prepared to make the critical allegations on these subjects and offer the necessary proof, the Complaint should be dismissed.

D. To the Extent that FDA Regulations Preclude Entry of Other Generics, Schering is Immune Under *Noerr-Pennington*

In its initial brief, Schering pointed out that it is not yet clear how the 180-day exclusivity provisions of the Hatch-Waxman Act will apply when a first generic filer *settles* a patent case by delaying its own entry into the market. Thus, it is not clear what the legal effect of the Upsher settlement is on the ability of other generics to enter the market. Congress may have intended for the first generic filer to be able to exclude other generics until the first filer enters the market under a settlement agreement. On the other hand, Congress may have intended for the first

generic filer to lose its exclusivity rights under such a settlement. The FDA and the courts are still working out the answer to this policy question.

Schering pointed out, more importantly, that the settlement agreements themselves say nothing on the subject of Upsher's exclusivity rights; and that if the courts and FDA conclude – as complaint counsel seems to assume they will – that a settling first filer does have exclusivity rights, those rights will result from a governmental policy decision, and no private antitrust liability may be based on that governmental decision.

In its response, complaint counsel exhibits continued confusion concerning the Hatch-Waxman exclusivity provisions; and complaint counsel badly misstates the Supreme Court's *Noerr* decision.

1. The Hatch-Waxman Act and Regulations

In the Complaint, the Commission alleges that "*[a]t all times relevant herein*, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked." Complaint ¶ 29 (emphasis added). *See also id.* ¶¶ 42, 50, 60, 66 (alleging that Upsher is entitled to 180-day exclusivity period). In its Response, however, complaint counsel now admits that "FDA's implementation of this exclusivity provision *has varied over the course of time covered by the complaint.*"[7]

In fact, the FDA regulations in existence at the time of the Upsher settlement provided, in effect, that a first filer who *settles* a patent case lost any exclusivity rights it might have had under Hatch-Waxman. These regulations remained in effect until they were withdrawn in April 1998. *See Guidance for Industry on 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 63 Fed. Reg. 37,890 (July 14, 1998). Thus, the Complaint's theory is wrong under the regulations in existence when Schering and Upsher entered into their settlement agreement.

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7 Response at 20 (emphasis added).

Thereafter, FDA proposed new regulations. Under those regulations, a first filer who *settles* patent litigation delaying the first filer's entry into the market would have its exclusivity rights terminate no later than a year after any other generic is ready to market its product. *See* 64 Fed. Reg. 42880. Thus, the Complaint's theory is wrong under the proposed regulations.

Complaint counsel correctly observes at page 23 of its Response that the proposed regulations are not yet effective. While they have been pending, FDA has been "regulating directly from the statute." *See* Schering's Memorandum at 14. And it appears from FDA's most recent regulatory interpretation of the statute that FDA believes a first filer who settles patent litigation delaying its own entry is *not* entitled to exclusivity. Thus, the Complaints' theory may well be wrong under the FDA's current application of the statute in the absence of any effective regulations. *See* Schering's Memorandum at 14-15.

The point is this: it is not clear what Congress intended the outcome to be when the first ANDA filer settles its patent case and agrees to delay its own entry. This question will be resolved either by the FDA or the courts. If the FDA or the courts determine that other generics should be blocked from the market until 180 days after the settling first filer enters, this could well be viewed as a restraint on competition. But the restraint will result from a governmental decision – a decision that the restraint is warranted by other policy considerations.

As complaint counsel correctly concedes, Schering would have been privileged after its settlement with Upsher to *lobby* FDA to adopt a rule blocking other generics from entering the market prior to Upsher's entry; and, if the lobbying achieved its objective and FDA adopted such a rule, Schering would have been *immune* from liability for the resulting restraint on competition. *A fortiori*, Schering cannot be held liable for the restraint if FDA reaches such a result on its own.

2. *Noerr*

Complaint counsel also asserts that the *Noerr* doctrine does not apply because the Complaint does not challenge any *petitioning* behavior on the part of Schering. Thus, complaint

counsel asserts that *Noerr*[8] applies only when the parties *petitioned* for the governmental restraint: "the inquiry into the source of the restraint only arises if the conduct at issue amounts to petitioning." Response at 17. Complaint counsel is plainly wrong on this point. A reading of *Noerr* itself reveals that the Supreme Court took it as a given that restraints flowing from government action or decision were not actionable, with or without petitioning.

The issue in the *Noerr* case was whether concerted lobbying activity by several railroads, including an allegedly misleading publicity campaign, conducted for the purpose of causing passage of laws which would harm their trucking competitors, violated the Sherman Act. In addressing this issue, the court stated certain *already established* principles "as a starting point for our consideration of the case." *Id.* at 135. The first of these was the principle established by prior cases that where a restraint on trade is the result of government action, no violation of the Sherman Act is made out. *Id.* at 136.

The Court stated "it has been held that where a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action, no violation of the Act can be made out." *Id.* at 136. With that proposition firmly stated, the court went on to consider the more difficult question whether the allegedly deceptive lobbying campaign engaged in by many railroads seeking to cause governmental action was itself a violation of the Sherman Act. The Court held that it was not. *Id.* at 136-145.

So while *Noerr* certainly involved petitioning, the Court's holding was based in important part on the *pre-existing* rule of law that restraints on trade resulting from governmental decisions are not actionable. The Court explained the decisions creating this pre-existing rule by saying that "these decisions rest upon the fact that under our form of government the question whether a law [restricting competition] should pass, or if passed be enforced, is the responsibility of the appropriate legislative or executive branch of government ... ." *Id.* at 136. Here, the question whether a settling first filer should be able to block competing generics under the Hatch-Waxman

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8 *Eastern Railroad Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961).

Act was the responsibility of Congress to decide, and if Congress' intent is unclear, it is for the FDA and the courts to decide what that intent was.

With all due respect, it is preposterous for complaint counsel to argue that Schering would be immune from antitrust liability if it had successfully lobbied FDA to adopt a regulation blocking third party generics from the market; but that Schering is liable if FDA adopted such a regulation on its own.

CONCLUSION

For the foregoing reasons and those set forth in Schering's Memorandum, partial dismissal of the complaint is warranted.

Respectfully submitted,

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Dated: July 6, 2001

CERTIFICATE OF SERVICE

I hereby certify that this 6th day of July, 2001, I caused an original, one paper copy and an electronic copy of the Reply in Support of Schering-Plough's Motion for Partial Dismissal to be filed with the Secretary of the Commission, and that two paper copies and an electronic copy were served by hand upon:

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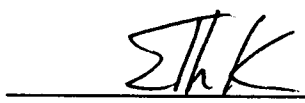

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